#### Citation:

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**PubMed ID: 19386574** 

### **Study Design:**

Prospective Cohort Study

#### Class:

B - Click here for explanation of classification scheme.

# **Research Design and Implementation Rating:**



POSITIVE: See Research Design and Implementation Criteria Checklist below.

# **Research Purpose:**

- To examine the associations of mean weight and variability about the mean, average weight change per year and episodes of weight cycling, with new onset of functional difficulties and mortality among persons aged 65 and older
- They hypothesized that higher weight and weight variability would predict incident functional impairment and that weight loss, variability and cycling would predict mortality in this older cohort, even after adjustment for self-reported health and comorbidities.

#### **Inclusion Criteria:**

- Aged 65 years and older
- Medicare eligibility from four communities: Sacramento County, California; Washington County, Maryland; Forsyth County, North Carolina; Pittsburgh, Pennsylvania and from age-eligible participants in the same household.

#### **Exclusion Criteria:**

Institutionalized, wheelchair bound in the home or under active treatment for cancer, including hospice care, radiation or chemotherapy.

# **Description of Study Protocol:**

#### Recruitment

Participants aged 65 years and older were recruited from random samples of Medicare eligibility lists in four communities: Sacramento County, California; Washington County, Maryland; Forsyth County, North Carolina; Pittsburgh, Pennsylvania and from age-eligible participants in the same household

### Design

- Semiannual contacts alternated between clinic visits and phone calls through 1999 and phone calls continue through the present time
- Components of the annual exams varied, but consistently included medical history, medication use, measurement of weight and self-reported health status
- In 2005 to 2006, participants were seen again in their home or the clinic to assess physical and cognitive function.

# **Dietary Intake/Dietary Assessment Methodology**

Not applicable.

#### **Blinding Used**

None reported.

#### Intervention

Not applicable

### **Statistical Analysis**

- Participants alive in 1998 to 1999 but excluded from the analysis due to insufficient data were compared against those included using chi-square tests for categorical variables and analysis of variance (ANOVA) for continuous measures
- Pearson correlation coefficients were computed to evaluate pairwise associations between the weight summary measures
- Participant characteristics and comorbidities were compared across weight pattern groups using chi-square tests and ANOVA as appropriate. Pairwise comparisons were assessed, using a Bonferroni correction for the overall P-value
- Cox proportional hazards regressions were used to estimate the relative risks associated with the weight summary measures for incident ADL difficulty, incident mobility difficulty and mortality
- The four weight summary measures were included simultaneously in the multivariable models. Incident ADL impairment and mobility impairment were computed from phone follow-up data between 1999 and 2005 and 2006 among participants without the difficulty in 1998 to 1999
- Dates of impairment were estimated as the median date between the time the impairment was first reported and the previous contact
- Participants with incomplete follow-up were censored after their last follow-up contact or death
- All analyses were adjusted for age, sex, race, height and high school education, measured at baseline and any of the following, determined in 1998 to 1999, that were significantly associated with the outcome: Current smoking, diabetes, osteoporosis, self-reported health, hypertension, lung ailments, cancer, congestive heart failure, coronary heart disease, claudication, stroke or transient ischemic attack. The significant covariate variables were entered first into the multivariable models, and associations of the continuous weight summary measures were assessed for non-linearity by examining residual plots and testing the significance of quadratic effects in the models. Interactions of mean weight with slope and interactions of the weight summary measures with sex and race were evaluated for significance

• Sensitivity analyses were performed that included only those participants who self-reported good to excellent health in 1998 to 1999, in order to reduce the likelihood that weight changes were due to poor health. Regression analyses were repeated using the weight pattern groups instead of the four weight summary measures for comparability with results reported in the literature.

### **Data Collection Summary:**

### **Timing of Measurements**

Enrollment: 1992-1999Follow-up: 2005-2006.

### **Dependent Variables**

- Variable 1: Weight, CV of weight, current smoker, diabetes, hypertension, congestive heart failure CHF), coronary heart disease (CHD), claudication, stroke, transient ischemic attack, osteoporosis, lung ailment, any cancer, fair or poor health, ADL difficulty, mobility difficulty
- Variable 2: Weight trajectory summaries: Mean weight (per 32 pounds), weight gain, weight variability, weight cycling
- Variable 3: Weight patterns: Loss, stable, gain, cycling (unstable).

### **Independent Variables**

- Weight change group as of 1992-1999: Weight gain, stable weight, weight gain, weight cycling
- Weight summary by outcome: Incident ADL, incident mobility disability, mortality.

#### **Control Variables:**

- Age
- Sex
- Race
- Height
- High school education
- Measured at baseline:
  - Current smoking
  - Diabetes
  - Osteoporosis
  - Self-reported health
  - Hypertension (HTN)
  - Lung ailments
  - Cancer
  - CHF
  - CHD
  - Claudication
  - Stroke
  - Transient ischemic attack (TIA).

### **Description of Actual Data Sample:**

- *Initial N*: 5,888 (57.6% women)
- Attrition (final N): 4,199 were alive at the time of follow-up and 3,963 (94.4%) were contacted. Of those, 3,278 (82.7%) had at least five measurements of weight and were included in the analysis for mortality
- Age: 72.8±5.6 years at enrollment
- Ethnicity: 15.7 % Black
- Other relevant demographics: Those included in the mortality analysis were healthier, younger and had less cognitive and functional disability than those excluded, but did not differ by baseline weight or average weight change (among those with at least two weight measurements)
- Anthropometrics:

# Table. Summaries of Weight History, 1992-1999

	Women, N=2,013	Men, N=1,265	All N=3,278	
Mean weight, pounds	150 (30.0)	176 (27.4)	160 (31.6)	
Weight change, pounds per year	-0.76 (2.22)	-0.68 (2.07)	-0.73 (2.16)	
Weight variability, <u>CV</u>	0.038 (0.024)	0.031 (0.020)	0.035 (0.022)	
Weight patterns, N (percent)				
Loss	688 (34.2)	369 (29.2)	1,057 (32.2)	
Stable	451 (22.4)	411 (32.5)	862 (26.3)	
Gain	391 (19.4)	241 (19.0)	632 (19.3)	
Cycling (unstable)	483 (24.0)	244 (19.3)	727 (22.2)	

Note: Entries are mean (SD) unless otherwise noted. lbs=pounds; CV=coefficient of variation

• *Location:* Sacramento County, California; Washington County, Maryland; Forsyth County, North Carolina; and Pittsburgh, Pennsylvania.

# **Summary of Results:**

The average weight change was a loss of approximately three-fourths pounds per year, with women losing more on average than men. Nearly one fourth of the women and one fifth of the men experienced weight cycling, 20% of whom had more than one episode of cycling.

- Changes in weight during the seven-year period were highly associated with participant characteristics and health status measures at the end of the period
- Participants who experienced weight loss or weight fluctuations were generally older, in poorer overall health, more likely to be current smokers and to have diabetes or CVD than those who remained stable or gained weight. ADL and mobility difficulty were greater in participants who experienced weight loss or fluctuations compared with those who remained stable or who gained weight
- After adjusting for age, sex, race, height, high school education, diabetes, cancer and

- self-reported health, higher mean weight, weight variability and weight cycling were associated with an increased risk of ADL impairment
- A history of weight cycling increased the risk of ADL difficulty by 28%, which is similar to those for diabetes and cancer
- After adjusting for age, sex, race, height, education, self-reported health, current smoking, diabetes, CHF, claudication, stroke, cancer, weight loss, weight variability and weight cycling were all associated with increased risk of mortality.

Table. Adjusted\* Hazard Ratios of Weight Summaries by Outcome

	Incident ADL†	Incident Mobility Difficulty‡	<b>Mortality</b> §
Number of cases per number at risk	1,350/2,492	1,537/2,136	1,072/3,278
Model 1. Trajectory sur	nmaries		
Mean weight, per 32 pounds	1.14 (1.07, 1.22);	1.16 (1.05, 1.20);	0.87 (0.81, 0.94);
	1.11 (1.04, 1.19)	1.12 (1.05, 1.20)	0.83 (0.77, 0.89)
Weight change, pounds per year	0.98 (0.95, 1.01);	1.01 (0.98, 1.04);	0.93 (0.90, 0.96);
	0.98 (0.95, 1.01)	1.01 (0.99, 1.04)	0.93 (0.91, 0.96)
Weight variability, per SD of <u>CV</u>	1.14 (1.08, 1.21);	1.11 (1.05, 1.18);	1.21 (1.14, 1.28);
	1.11 (1.05, 1.17)	1.07 (1.01, 1.13)	1.13 (1.07, 1.20)
Weight cycling	1.30 (1.14, 1.50);	1.25 (1.09, 1.42);	1.39 (1.21, 1.61);
	1.28 (1.12, 1.47)	1.25 (1.09, 1.42)	1.20 (1.04, 1.39)
Model 2. Weight patterns#			
Loss	1.32 (1.15, 1.53);	1.14 (1.00, 1.31);	1.82 (1.54, 2.17);
	1.27 (1.10, 1.46)	1.08 (0.95, 1.24)	1.58 (1.33, 1.88)
Stable	1.00 (ref)	1.00 (ref)	1.00 (ref)
Gain	1.04 (0.88, 1.23);	1.10 (0.95, 1.27);	1.14 (0.92, 1.40);
	1.03 (0.87, 1.22)	1.06 (0.91, 1.22)	1.10 (0.89, 1.36)
Cycling (unstable)	1.64 (1.40, 1.92);	1.44 (1.25, 1.67);	2.20 (1.83, 2.63);
	1.54 (1.32, 1.80)	1.36 (1.18, 1.58)	1.66 (1.38, 2.00)

*Notes:* ADL=activities of daily living; CHD=coronary heart disease; CHF=congestive heart failure; CV=coefficient of variance; lbs=pounds; TIA=transient ischemic attack.

- \* Results in the first rows are adjusted for age, sex, height, race and high school education. Results in the second rows are additionally adjusted for self-reported health and comorbidities, with specific adjustment variables given in the footnotes.
- † Additionally adjusted for diabetes, cancer and self-reported poor or fair health.
- ‡ Additionally adjusted for diabetes, HTN, CHF, CHD, TIA, cancer and self-reported poor or fair health.
- § Additionally adjusted for diabetes, CHF, claudication, stroke, current smoking, cancer and

self-reported poor or fair health.

- ? Thirty-two pounds is 1 SD.
- ¶ At the overall mean weight of 160 pounds; quadratic association found.
- # Additionally adjusted for starting weight.

#### **Author Conclusion:**

- Monitoring the weight of an older person for fluctuations or episodes of both loss and gain is an important aspect of geriatric care
- Patients who are able to maintain a stable weight through periods of illness may represent those with better homeostatic control and conversely, those who are unable to maintain a stable weight may be at increased risk for physical disability or mortality.

#### **Reviewer Comments:**

- The authors noted the following strengths of their work:
  - Use of measured rather than self-reported weights
  - A focus on current weights in older persons, rather than comparisons with recalled weights at an earlier age
  - Enough repeated weight measurements to capture weight cycling
  - Seven years of follow-up beyond the weight trajectory measures
  - Adjustment for risk factors and health status at the end of the trajectory
- *The authors noted the following limitations of their work:* 
  - They have not considered intentionality of weight changes.

#### Research Design and Implementation Criteria Checklist: Primary Research

### **Relevance Questions**

1. Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)

N/A

2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?

Yes

3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?

Yes

4. Is the intervention or procedure feasible? (NA for some epidemiological studies)

N/A

# **Validity Questions**

1. Was the research question clearly stated?

Yes

	1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
	1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
	1.3.	Were the target population and setting specified?	Yes
2.	Was the sele	ection of study subjects/patients free from bias?	Yes
	2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
	2.2.	Were criteria applied equally to all study groups?	Yes
	2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
	2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	Were study	groups comparable?	Yes
	3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
	3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	No
	3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
	3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
	3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
	3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	Was method of handling withdrawals described?		
	4.1.	Were follow-up methods described and the same for all groups?	Yes
	4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes

	4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
	4.4.	Were reasons for withdrawals similar across groups?	Yes
	4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	Was blindin	g used to prevent introduction of bias?	No
	5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
	5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
	5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	No
	5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
	5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.		ention/therapeutic regimens/exposure factor or procedure and ison(s) described in detail? Were interveningfactors described?	Yes
	6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
	6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
	6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
	6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	???
	6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
	6.6.	Were extra or unplanned treatments described?	Yes
	6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
	6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	Were outcom	mes clearly defined and the measurements valid and reliable?	Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	N/A

	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes		
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes		
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes		
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes		
	7.7.	Were the measurements conducted consistently across groups?	Yes		
8.	Was the stat outcome ind	tistical analysis appropriate for the study design and type of licators?	Yes		
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes		
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes		
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes		
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes		
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes		
	8.6.	Was clinical significance as well as statistical significance reported?	Yes		
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	No		
9.	Are conclusions supported by results with biases and limitations taken into consideration?				
	9.1.	Is there a discussion of findings?	Yes		
	9.2.	Are biases and study limitations identified and discussed?	Yes		
10.	Is bias due to	o study's funding or sponsorship unlikely?	Yes		
	10.1.	Were sources of funding and investigators' affiliations described?	Yes		
	10.2.	Was the study free from apparent conflict of interest?	Yes		